that date, unless FDA has made a determination that the drug has not been shown to be safe or lacks substantial evidence of effectiveness under the DESI program. FDA is proceeding under its DESI program to establish regulations under section 507 to provide for certification of those drugs only if they have been shown to be safe and effective.

[50 FR 7516, Feb. 22, 1985]

PART 431—CERTIFICATION OF ANTIBIOTIC DRUGS

Subpart A—General Provisions

Sec.

431.1 Requests for certification, check tests and assays, and working standards; information and samples required.
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431.10 Certification.
431.11 Conditions on the effectiveness of certificates.
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Subpart D—Confidentiality of Information

431.70 Confidentiality of data and information in an investigational new drug notice for an antibiotic drug.

AUTHORITY: Secs. 501, 502, 503, 505, 507, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 353, 355, 357, 376); secs. 215, 301, 351 of the Public Health Service Act (42 U.S.C. 216, 241, 262); 5 U.S.C. 552.

SOURCE: 39 FR 18934, May 30, 1974, unless otherwise noted.

Subpart A—General Provisions

§ 431.1 Requests for certification, check tests and assays, and working standards; information and samples required.

(a) A request for certification of a batch (antibiotic Form 7/Form FDA–1677) is to be addressed to the Food and Drug Administration, Division of Research and Testing (HFD–470), 200 C St. SW., Washington, DC 20204.

(b) [Reserved]

(c) A person who requests certification or check tests and assays of a batch shall submit with his request the following information and samples:

(1) The batch mark of the drug.

(2) The quantity of each ingredient used in making the batch and a statement that each such ingredient conforms to the requirements or standards prescribed therefor, if any, by specific regulations or official compendium or otherwise approved by the Commissioner.

(3) The size of the batch, including the number of containers of each size in the batch.

(4) The date of the latest assay of the batch.

(5) The results of the latest tests and assays made by or for him on the batch as required for the drug by specific regulations.

(6) The batch mark(s) of the antibiotic(s) used in making the batch.

(7) Unless previously submitted, the results and dates of the latest tests and assays made by or for him on the antibiotic(s) used in making the batch as required by specific regulations.

(8) The number of accurately representative samples that are required for the batch by specific regulations:

(i) In the case of drugs such as dry powders, solutions, ointments, and suspensions, the sample shall be collected by taking single immediate containers, before or after labeling, at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal. In no case,

however, shall more than 5,000 immediate containers have been packaged during each such interval of sampling, except for a sample collected for sterility testing.

(ii) In the case of drugs in unit dosage forms, such as tablets, capsules, or suppositories, samples shall be collected as follows:

(*a*) From batches exceeding 500,000 units, a representative sample consisting of 100 units shall be collected by taking single units at approximately equal intervals throughout the final production of the batch. If the person packaging the units into dispensing-size containers is not the manufacturer, the representative sample consisting of 100 units shall be collected by taking single units at approximately equal intervals during packaging.

(*b*) From batches of 500,000 units or less, a representative sample consisting of not more than 100 units shall be collected by taking single units at approximately equal intervals throughout the final production of the batch. If the person packaging the units into dispensing-size containers is not the manufacturer, the samples shall be collected by taking single units at approximately equal intervals during packaging. In no case shall more than 5,000 units be produced or packaged during a sampling interval. The minimum acceptable sample size shall be as specified in the appropriate monograph.

(*c*) When the manufacturing process is such that it is not feasible to collect the samples throughout the final production of the batch (e.g., if tablets undergo further processing, such as polishing or coating, after being compressed), the samples may be collected from bulk containers of the finished product, according to the following requirements:

(*1*) For batches exceeding 500,000 units: If the batch is in more than 100 containers, the sample is 1 unit from each container. If the batch is in 100 containers or less, the sample is 100 units, taken in approximately equal amounts from each container.

(*2*) For batches of 500,000 units or less: If the batch is in more than 100 containers, the sample is 1 unit from each container. If the batch is in 100 containers or less, the sample is at least 1 unit for every 5,000 units in the batch taken in approximately equal amounts from each container. The sample shall not be less than the minimum number of units specified in the appropriate monograph.

(iii) In the case of drugs packaged for repacking or for use in the manufacture of another drug, the sample must be representative of the batch. Such samples may be taken from a composite composed of portions taken from a representative number of bulk containers, the composite consisting of no more than 10 times the amount required for conducting the required tests and assays. Such samples are not required if they have been previously submitted.

(iv) In the case of a sterile drug packaged in combination with containers of a sterile diluent, the sample shall be collected by taking 20 immediate containers of the diluent collected at regular intervals throughout each filling operation, except that if the diluent is sterilized after filling into containers, the representative sample shall consist of 20 immediate containers collected from each sterilizer load and each container shall be taken from a different part of each such sterilizer load. In the case of sterile drugs packaged in combination with sterile dispensers, the sample shall be collected by taking 20 dispensers from each sterilizer load, and each dispenser shall be taken from a different part of such sterilizer load.

(9) In the case of an initial request for certification, each ingredient used in making the batch other than ingredients required by specific regulations: 1 package of each containing approximately 5 grams. Results and dates of the latest tests and assays made by or for him on such ingredients shall precede or accompany the submission.

(10) The results and dates of tests and assays made by or for him on the nonantibiotic active ingredients in the batch.

(11) If such batch or any part thereof is to be packaged with a sterile diluent or sterile dispenser, such request shall also be accompanied by a statement that such diluent or dispenser is sterile

and conforms to the requirements prescribed therefor by specific regulations.

(d) Each sample submitted pursuant to the regulations in this chapter shall be addressed to the Commissioner. Its package shall be clearly identified as to its contents and shall bear the name and post-office address of the person submitting it.

(e) In addition to the information and samples specifically required to be submitted to the Commissioner by the regulations in this chapter, the person who requests certification of a batch shall submit such further information and samples as the Commissioner may require for the purpose of investigations to determine whether or not such batch complies with the requirements of §431.10 for the issuance of a certificate.

(f) Reference standards identical to working standards are available from: U.S.P. Reference Standards, 12601 Twinbrook Parkway, Rockville, Md. 20857, 301–881–0666.

[39 FR 18934, May 30, 1974, as amended at 41 FR 46852, Oct. 26, 1976; 43 FR 41195, 41197, Sept. 15, 1978; 45 FR 40111, June 30, 1980; 50 FR 7516, Feb. 22, 1985; 50 FR 8997, Mar. 6, 1985; 55 FR 11582, Mar. 29, 1990]

§431.5 Samples for sterility testing.

(a) *''Filling operation'' and ''sample'' defined.* (1) The term ''filling operation'' when used in connection with samples of a batch required for sterility testing refers to that period of time not longer than 24 consecutive hours during which a homogeneous quantity of drug is being filled continuously into market-size containers and during which no changes are made in the equipment used for filling. (Short rest periods for operators of the filling equipment and the time required to change operators between consecutive shifts are not considered as a break in continuity of the filling operation.) If more than one filling device is used during the filling operation, the samples shall include immediate containers filled by each device, and each such container shall be identified with a mark corresponding to that assigned to the filling device. If more than one filling operation is required to fill a batch, each container in the sample shall be identified with the number of the operation.

(2) For the purpose of sterility testing, the term ''sample'' means the total number of containers taken from each filling operation.

(b) *Packaging requirements for samples.* If a batch of a sterile antibiotic is packaged for repacking or for use as an ingredient in the manufacture of another drug, the sample required for sterility testing may be packaged in one container, in lieu of 20 containers, or in two containers in lieu of 40 containers, under the following conditions:

(1) The weight or volume of the sample is equivalent to the composite weight or volume required for a multiple container sample;

(2) The sample is a composite of samples taken from all parts of the batch; and

(3) The sterility test method prescribed for the drug by the regulations in this chapter is ''Bacterial membrane filter method'' described in §436.20(e)(1) of this chapter.

§431.10 Certification.

(a) If it appears to the Commissioner, after such investigation as he considers necessary, that:

(1) The information (including results of tests and assays) and samples required by or pursuant to the regulations in this chapter have been submitted, and the request for certification contains no untrue statement of a material fact; and

(2) The batch complies with the regulations in this chapter and conforms to the applicable standards of identity, strength, quality, and purity prescribed by the regulations in this chapter;

the Commissioner shall certify that such batch is safe and efficacious for use, subject to such conditions on the effectiveness of certificates as are prescribed by §431.11 and shall issue to the person who requested it a certificate to that effect.

(b) If the Commissioner determines, after such investigation as he considers to be necessary, that the information submitted pursuant to the regulations in this chapter, or the batch covered by such request, does not comply with the requirements set forth in paragraph (a)

of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who requested certification, stating his reasons for refusal.

(c) All statements, samples, and other information and materials submitted in connection with a request for certification shall be considered to be part of such request.

(d) Compliance of a drug with the standards of identity, strength, quality, and purity prescribed by regulations in this chapter shall be determined by the tests and methods of assay prescribed for such drug by regulations issued under this chapter.

(e) The regulations in this chapter, prescribing tests and methods of assay for antibiotic and antibiotic-containing drugs, shall not be construed as preventing the Commissioner from using any other test or method of assay in his investigations to determine whether or not:

(1) A request for certification contains any untrue statement of a material fact; or

(2) A certification has been obtained through fraud, or through misrepresentation or concealment of a material fact.

(f) Except as specifically provided by the regulations in this chapter, no provision of any regulation shall be construed as exempting any certifiable antibiotic drug from any applicable provision of the act or any regulation thereunder.

§431.11 Conditions on the effectiveness of certificates.

(a) A certificate shall not become effective:

(1) If it is obtained through fraud or through misrepresentation or concealment of a material fact;

(2) With respect to any package unless it complies with the packaging requirements, if any, prescribed by the regulations in this chapter which were in effect on the date of the certificate;

(3) With respect to any package unless its label and labeling bear all words, statements, and other information required by the regulations in this chapter; or

(4) With respect to any package of a certifiable antibiotic drug subject to the regulations in this chapter, when it is included in a packaged combination with another drug, unless such other drug complies with the requirements of the regulations in this chapter.

(b) A certificate shall cease to be effective:

(1) With respect to any immediate container after the expiration date, if any, prescribed by the regulations in this chapter;

(2) With respect to any immediate container when it or its seal (if the regulations in this chapter require it to be sealed) is broken, or when its label or labeling is altered, multilated, destroyed, obliterated, or removed in whole or in part, or ceases to conform to any labeling requirement prescribed by the regulations in this chapter, except that:

(i) If the drug in such container is repacked or used as an ingredient in the manufacture of another drug, and certification of the batch thus made is requested, such certificate shall continue to be effective for a reasonable time to permit certification or destruction of such batch;

(ii) If the drug is in a container packaged for dispensing and is used in compounding a prescription issued by a practitioner licensed by law to administer such drug, such certificate shall continue to be effective for a reasonable time to permit the delivery of the drug compounded on such prescription; or

(iii) If its label or labeling is removed in whole or in part for the purpose of relabeling and supplemental certification of the relabeled drug is requested, as provided by §433.12 of this chapter.

(3) With respect to any immediate container of penicillin when it is included in the packaged combination penicillin with aluminum hydroxide gel or penicillin with a vasoconstrictor, or to any immediate container of bacitracin when it is included in the packaged combination bacitracin with a vasoconstrictor, except that when certification of the batch so included is requested, such certificate shall continue to be effective for a reasonable time to permit certification of such

batch which is part of such combination;

(4) With respect to any package when the drug therein fails to meet the standards of identity, strength, quality, and purity which were in effect on the date of the certificate; except that those minor changes which occur before the expiration date and which are normal and unavoidable in good storage and distribution practice shall be disregarded.

(5) With respect to any package of a certifiable antibiotic drug subject to the regulations in this chapter, included in a packaged combination with another drug, when such other drug fails to meet the requirements of the regulations in this chapter; or

(6) With respect to any immediate container, if such regulations require its labeling to bear a caution against dispensing otherwise than on prescription, at the beginning of the act of dispensing or offering to dispense it otherwise than:

(i) By a practitioner licensed by law to administer such drug; or

(ii) On his prescription issued in his professional practice.

§ 431.12 Certification of antibiotic drugs after shipment in bulk containers.

(a) The Food and Drug Administration has received inquiries from certain interested manufacturers concerning their shipment of certified antibiotics, packaged in bulk containers, to hospitals and pharmacies for repacking or for use in the manufacture of another drug on the order or prescription of a physician. The regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) do not prohibit the shipment of certified bulk containers of antibiotics to such persons. However, under the provisions of § 431.11(b)(2)(i), certification should be requested of each repacked batch and of each batch of another drug manufactured from such bulk drug, unless the repackaged drug or other drug has been made exempt from the certification requirements by regulation. The fact that the drug is to be repacked or manufactured on the order or prescription of a physician does not exempt it from the certification requirements of the act. Under the provisions of § 431.11(b)(2)(ii), it is only when the drug used to compound a prescription is in a container packaged for dispensing that certification of the drug so compounded is not required.

(b) In the light of these provisions, unless the manufacturer and shipper of bulk containers of antibiotics has, with the consignee, an effective permit issued under § 433.16 of this chapter, if the drug is to be repacked, or under § 433.13 of this chapter if it is to be used in the manufacture of another drug, the shipper has the responsibility of seeing that certification is requested of each repacked batch and of each batch of another drug manufactured from such drug.

§ 431.17 Request to provide for certification of an antibiotic drug.

A request under section 507 of the Federal Food, Drug, and Cosmetic Act to provide for certification of an antibiotic drug is required to comply with the procedures and meet the requirements applicable to the submission to the Food and Drug Administration and review by the agency of applications and abbreviated applications, and amendments and supplements to them, under part 314 of this chapter.

[50 FR 7516, Feb. 22, 1985]

§ 431.20 Disposition of outdated drugs.

When certification becomes invalid because the expiration date is passed, such articles should not be disposed of for drug use either through commercial or charitable channels unless the articles have been assayed to establish potency and recertified.

Subpart B—Administrative Procedures

§ 431.50 Forms for certification or exemption of antibiotic drugs.

The following forms which must be supplied in connection with certain certification or exemption procedures for antibiotic drugs may be obtained from the Product Surveillance Branch (HFD–333), Food and Drug Administration, Department of Health and Human

Services, 5600 Fishers Lane, Rockville, MD 20857.

Form

1 Application for exemption for storage.
2 Application for exemption for processing.
3 Application for exemption for labeling.
4 Application for exemption for manufacturing use.
7 Request for check tests and assays or certification of a batch of _____(the blank to be filled in with the name of the antibiotic drug).
8 Application for exemption for repacking.
9 Request for supplemental certification of a batch of an antibiotic drug.

[39 FR 18934, May 30, 1974, as amended at 40 FR 28052, July 3, 1975; 41 FR 10886, Mar. 15, 1976; 50 FR 7516, Feb. 22, 1985; 50 FR 8997, Mar. 6, 1985; 55 FR 11582, Mar. 29, 1990]

§ 431.51 Suspension of certification service.

When the Commissioner finds that a person has:

(a) Obtained or attempted to obtain a certificate through fraud or through misrepresentation or concealment of a material fact; or

(b) Falsified the records required to be kept by § 431.61; or

(c) Failed to keep such records or to make them available, or to accord full opportunity to take an inventory of stocks on hand, or otherwise to check the correctness of such records as required by § 431.61; or

(d) Failed to establish a system for maintaining the records required by § 314.81 of this chapter or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with the provisions of that section, or has refused to permit access to, or copying, or verification of such records or reports; or

(e) Failed to conform to the requirements of good manufacturing practice prescribed by parts 210, 211, 225, 226 and 229 of this chapter;

the Commissioner will immediately suspend service to such person under the regulations in this chapter. Upon request a hearing will be granted to such person to show cause why such service should be resumed.

[39 FR 18934, May 30, 1974, as amended at 40 FR 13497, Mar. 27, 1975; 55 FR 11582, Mar. 29, 1990]

§ 431.52 Hearings.

Any person who contests the suspension of certification service under § 431.51 shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

[41 FR 48267, Nov. 2, 1976, as amended at 42 FR 15675, Mar. 22, 1977]

§ 431.53 Fees.

(a) Fees for the services rendered under the regulations in this chapter shall be such as are necessary to provide, equip, and maintain an adequate certification service.

(b) The fee for such services with respect to each batch of a drug, certification of which is provided by the regulations in this chapter, shall be $114 for each batch submitted, plus the sum of the fees for all individual tests required for certification of each batch. The minimum tests for each batch shall be those prescribed in the section relating specifically to such drug.

(1) The fee schedule for specific tests required for antibiotic drug certification is as follows:

CHARGEABLE FEE PER TEST

Arquad content	$20
Benzylpenicilloyl content	32
Bleomycin	1,291
Butanol content	52
Candicidin potency (special turbidimetric)	85
Capreomycin 1 content	121
Color identity	8
Column chromatography	130
Column chromatographic isomer content	65
Copper content	22
Crystallinity	4
Cycloserine color assay	27
Daunorubicin potency (special turbidimetric)	19
Depressor substance test	40
Disc potency	52
Dissolution test	107
Doxycycline purity (paper chromatography)	130
Free chloride	54
Frozen antibiotic test panel	32
Gas chromatography	32
Gentamicin C	165
Heavy metals test	14
High pressure liquid chromatography (HPLC)	54
Infrared identity	19
Infrared quantitative	19
Iodochlorhydroxyquin content	22
Isoniazid content	22
Karl Fischer moisture	8
LD_{50} toxicity	185
Loss on drying	12
Lysine content	161
Melting range	8
Metal particles (ophthalmic ointments)	22
Microbiological assay, plate	50
Microbiological assay, turbidimetric	29

CHARGEABLE FEE PER TEST—Continued

Microorganism count	68
Nonaqueous titrations (and complexiметric)	22
Paper chromatographic identity	43
Penicillenate and penamaldate content	30
Penicillin chemical assay	15
Penicillin contamination	39
Penicillin G content	32
pH	4
Polarographic assay	33
Potency (special plate)	91
Probenecid content	32
Procaine colorimetric	8
Pyrogens test: 3 rabbits	72
Pyrogens test: 8 rabbits	144
Quantitative thin layer chromatography	80
Residual streptomycin	8
Residue on ignition	26
Solubility identification	54
Specific rotation	22
Specific rotation (potency quantitative)	44
Specific surface area	22
Sterility test	68
Sulfate content	8
Tablet disintegration	5
Thin layer chromatographic identity	43
Total Chlorine	54
Ultraviolet absorptivity	32
Ultraviolet identity	32
Ultraviolet potency	32
Vancomycin identity (bioautograph)	117
Zinc titration	11

(2) The fee for a supplemental request submitted pursuant to the provisions of § 433.12 of this chapter shall be $50.

(3) [Reserved]

(4) In the case of persons using the certification services and whose manufacturing facilities are not located in the United States or the Commonwealth of Puerto Rico, such persons shall be required to deposit each year sufficient funds to cover costs encountered when their facilities are inspected pursuant to the provisions of section 704 of the act.

(c) When the Commissioner considers it necessary to make investigations of a new product containing a certifiable antibiotic drug on which a request has been submitted in accordance with § 431.17, the fee for such service shall be the cost thereof. In such case the request shall be followed by an advance deposit in such amount as the Commissioner specifies, and thereafter such additional advance deposits shall be made as the Commissioner estimates may be necessary to prevent arrears in the payment of such fee.

(d) A person requiring continuing certification services may maintain an advance deposit of the estimated cost of such services for a two-month period. Such deposit shall be debited with fees for services rendered, but shall not be debited for any fee the amount of which is not definitely specified in the regulations in this chapter unless the depositor has previously requested the performance of the services to be covered by such fee. A monthly statement for each such advance deposit shall be rendered.

(e) The fees for the services rendered with respect to each batch certified under the regulations in this chapter shall accompany the request for certification, or the request for check tests and assays, unless such fee is covered by an advance deposit maintained in accordance with paragraph (d) of this section. Also, if the Commissioner considers that investigations other than examination of such samples are necessary to determine whether or not such batch complies with the requirements of § 431.10 for the issuance of a certificate, the fee shall include the cost of such investigations.

(f) The unearned portion of any advance deposit shall be refunded to the depositor upon his application.

(g) Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except for those services described under § 433.12 of this chapter.

(h) All deposits and fees required by the regulations in this chapter, shall be paid by money order, bank draft, or certified check drawn to the order of the Food and Drug Administration, collectible at par at Washington, DC. All such deposits and fees shall be forwarded to the Food and Drug Administration, Department of Health and Human Services, Accounting Branch (HFA–120), 5600 Fishers Lane, Rockville, MD 20857, whereupon after making appropriate records thereof they will be transmitted to the Chief Disbursing Officer, Division of Disbursement, Treasurer of the United States,

for deposit to the special account ''Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration.''

[39 FR 18934, May 30, 1974, as amended at 40 FR 13497, Mar. 27, 1975; 40 FR 28052, July 3, 1975; 41 FR 2384, Jan. 16, 1976; 41 FR 18291, May 3, 1976; 44 FR 67113, Nov. 23, 1979; 45 FR 16471, Mar. 14, 1980; 46 FR 16677, Mar. 13, 1981; 46 FR 60578, Dec. 11, 1981; 46 FR 61071, Dec. 15, 1981; 50 FR 19918, May 13, 1985; 55 FR 11582, Mar. 29, 1990]

Subpart C—Records and Reports

§ 431.61 Records of distribution.

(a) The person who requested certification shall keep complete records showing each shipment and other delivery (including exports) of each certified batch or part thereof by such person or by any person subject to his control. Such records shall show the date and quantity of each such shipment or delivery and the name and post-office address of the person to whom such shipment or delivery was made, and shall be kept for not less than 3 years after such date.

(b) Upon the request of any officer or employee of the Food and Drug Administration, or of any other officer or employee of the United States acting on behalf of the Secretary, the person to whom a certificate is issued shall at all reasonable hours make such records available to any such officer or employee and shall accord to him full opportunity to make inventory of stocks of such batch on hand and otherwise to check the correctness of such records.

§ 431.62 Records retention.

At the option of the person having control of records required to be kept by any regulation in this part 431, photostatic or other permanent reproductions may be substituted for such records after the first 2 years of the holding period.

Subpart D—Confidentiality of Information

§ 431.70 Confidentiality of data and information in an investigational new drug notice for an antibiotic drug.

(a) The existence of an IND notice for an antibiotic drug will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in an IND file for an antibiotic drug shall be handled in accordance with the provisions established in § 314.430 of this chapter.

(c) Notwithstanding the provisions of § 314.430 of this chapter, the Food and Drug Administration shall disclose upon request to an individual on whom an investigational antibiotic has been used a copy of any adverse reaction report relating to such use.

[39 FR 44655, Dec. 24, 1974, as amended at 50 FR 7517, Feb. 22, 1985]

PART 432—PACKAGING AND LABELING OF ANTIBIOTIC DRUGS

Sec.

432.1 Packaging requirements.
432.5 Labeling requirements.
432.9 Labeling of antibiotic drugs intended for export.
432.20 Declaration of potency.

AUTHORITY: Secs. 201, 301, 502, 503, 507, 701, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 352, 353, 357, 371, 381).

CROSS REFERENCE: For other regulations in this chapter concerning antibiotic drugs exempted from certain labeling requirements, see also § 201.150 of this chapter.

§ 432.1 Packaging requirements.

Each antibiotic drug subject to certification under section 507 or 512(n) of the act shall be packaged in immediate containers which shall be of such composition as not to cause any change in the strength, quality, or purity of the contents beyond any limits therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The immediate containers shall be tight containers as defined by the U.S.P., except that if the antibiotic drug is dispensed as an ointment or cream, the immediate containers shall be well-closed containers as defined by the U.S.P. If the antibiotic drug is packaged for dispensing, it may be packaged in combination with a container of a suitable and